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CHRIS COLE and CRISTY COLE

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

CHRIS COLE and
CRISTY COLE,

Plaintiffs,

v.

WRIGHT MEDICAL TECHNOLOGY, INC., a Delaware corporation,

Defendant.

Case No. _____

COMPLAINT FOR DAMAGES

1. Strict Products Liability – Manufacturing Defect
2. Strict Products Liability – Failure to Warn
3. Negligence
4. Fraudulent Misrepresentation
5. Fraudulent Concealment
6. Negligent Misrepresentation
7. Loss of Consortium

DEMAND FOR JURY TRIAL

Plaintiffs, Chris and Cristy Cole, by and through their attorneys of record, hereby file this Complaint for Damages and Jury Trial Demand against Defendant Wright Medical Technology, Inc., a Delaware corporation, to allege the following causes of action against Defendant, as follows:

NATURE OF THE ACTION

1. Defendant has known for years that its femoral stem hip replacement device – the PROFEMUR® Total Hip Femoral System with PROFEMUR® Femoral Stem (the "Stem") and PROFEMUR® Titanium Modular Neck (the "Neck") (collectively referred to as "the PROFEMUR® Total Hip Femoral System" or "the Device") – was prone to catastrophically fail within a few years of implantation despite representations to the contrary. The Stem and Neck of Defendant's Device is comprised of titanium alloy and is prone to micromotion, fretting and corrosion that leads to catastrophic fracture. Defendant has known since the 1990's that its Device has a tendency to fret, corrode and fracture at the location of the highest tensile stress concentration in the Neck-Stem-body transition during even low to moderate physical activity. As a result of the Device's defects and Defendant's tortious acts/omissions, Plaintiff Chris Cole, and many other patients who received these devices, endured unnecessary pain and suffering; debilitating lack of mobility; and a subsequent more difficult revision surgery to replace the faulty Device, giving rise to more pain and suffering, prolonged recovery time, disability, and increased

risk of complications and death from surgery.

2. Plaintiff Chris Cole has suffered from unnecessary pain, debilitation, risk of death, extended hospitalization and extended rehabilitation as necessitated a very complex revision surgery because of the catastrophic failure of Defendant's defective Device.

PARTIES

3. Plaintiffs Chris Cole and Cristy Cole are, and all times relevant hereto were, residents and citizens of Santa Barbra County, California.

4. Plaintiff Chris Cole underwent a right total hip arthroplasty on April 4, 2007. At that time, the PROFEMUR® Total Hip System manufactured, designed, distributed, labeled, marketed, and warranted by Defendant Wright Medical Technology, Inc. was implanted into Plaintiff Chris Cole. Plaintiff's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hip replacement surgery. The PROFEMUR® Total Hip System implanted on Plaintiff's right side subsequently failed by catastrophic fracture on February 12, 2019, and necessitated revision surgery.

5. Defendant Wright Medical Technology, Inc. (hereinafter "Wright" or "Wright Medical") is a corporation organized under the laws of the State of Delaware, with its principal place of business located in Memphis, Tennessee, and as such is a citizen of both the State of Tennessee and the State of Delaware.

Defendant Wright is registered to do business in the State of California, and may be served with process by serving its registered agent for service, Corporation Service Company, at 2710 Gateway Oaks Drive, Sacramento, California 95833.

6. At all times relevant hereto, the Defendant was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third-parties or related entities, numerous prosthetic orthopedic products, including the PROFEMUR® Total Hip System.

7. At all times relevant hereto, the Defendant was also involved in the business of monitoring and reporting adverse events concerning the PROFEMUR® Total Hip System, and participated in the decision process and response, if any, related to these adverse events.

8. At all times relevant hereto, either directly or through its agents, apparent agents, servants, or employees, the Defendant sold, distributed, and marketed the defective PROFEMUR® Total Hip Femoral System in the State of California. Defendant derives substantial revenue from orthopedic products used or implanted in the State of California. As such, Defendant expected or should have expected that its business activities could or would subject it to legal action in the State of California.

JURISDICTION AND VENUE

9. This Court has personal jurisdiction over the Defendant because it has sufficient minimum contacts with the State of California. At all times relevant hereto, Defendant directly or through its agents conducted regular and sustained business in California by selling and distributing its products in California, and engaged in substantial commerce and business activity in the County of Santa Barbara.

10. Defendant derives substantial revenue from orthopedic products used or implanted in the State of California. Defendant Wright's website lists approximately 200 doctors in California who have used Defendant Wright's products. As such, Defendant expected or should have expected that its business activities could or would subject it to legal action in California.

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the Parties are completely diverse in citizenship—Plaintiffs are California citizens and Defendant is a citizen of both Tennessee and Delaware—and the amount in controversy exceeds $75,000.

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) and (b)(2), as a substantial part of the events or omissions giving rise to this claim occurred in the County of Santa Barbara.

STATEMENT OF FACTS

13. In December 1999, Wright acquired Cremascoli Ortho ("Cremascoli"), a European manufacturer of artificial hip devices which had designed and manufactured artificial hips with a modular neck component since approximately 1985.

14. Pursuant to the Section 510(k) Premarket Notification Process ("510(k) Process"), on December 13, 2000, Wright received permission from the United States Food and Drug Administration ("FDA") to distribute in the United States its PROFEMUR® Femoral Hip System.

15. The FDA never considered and approved the safety of the PROFEMUR® Total Hip Femoral System, but instead concluded only that the PROFEMUR® was substantially equivalent to an already legally marketed device.

16. Sometime after December 13, 2000, Wright began to manufacture, label, market, promote, distribute, and sell in the United States the Wright Medical PROFEMUR® Femoral Hip System and its components, including the PROFEMUR® modular necks.

17. The Wright Medical PROFEMUR® modular necks that were distributed after December 13, 2000, and before August 25, 2009, were all made of a titanium-aluminum-vanadium alloy known as Ti6A14V.

18. On August 25, 2009, pursuant to a subsequent Section 510(k)

Premarket Notification (No. K091423), the FDA permitted Wright to distribute and market a PROFEMUR® device manufactured from cobalt chrome alloy instead of Ti6A14V, concluding – without assessing the safety of the device – only that the cobalt chrome alloy device is "substantially equivalent" to the Ti6A14V device.

19. The PROFEMUR® modular neck made of Ti6A/4V was still made available for sale after 2011, but only after a waiver was signed by the patient stating the patient understood the risks of fracture of the device.

20. The Wright Medical PROFEMUR® modular necks, as promoted, marketed, distributed, and sold in the United States after December 13, 2000, for use with various Wright Medical hip systems, were manufactured in twelve models or styles, six of those twelve were generally identified by Wright as "short" necks (i.e., Catalog #s PHA0-1202, PHA0-1212, PHA0-1222, PHA0-1232, PHA0-1242, and PHA0-1252), and six identified by Wright as "long" necks (i.e., Catalog #s PHA0-1204, PHA0-1214, PHA0-1224, PHA0-1234, PHA0-1244, and PHA0-1254).

21. In various marketing and promotional materials published and distributed by Wright from approximately the year 2002, and into the year 2005, and available to Wright's sales representatives and distributors, surgeons, patients, and the general public, Wright made the following representations, statements, claims, and guarantees about its PROFEMUR® modular necks:

The modular neck used with the Profemur Hip has been employed by

> Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur Hip. None of the necks has experienced a clinical failure since their inception.
>
> [emphasis added]

and

> The modular neck system, designed by Cremascoli in 1985 (U.S. Patent #4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees:
>
> - Structural reliability
> - Absence of significant micromovement
> - Absence of fretting corrosion
>
> [emphasis added]

[Wright Medical Technical Monograph MH688-102 ©2004].

22. In 2001, Wright made a design change to its PROFEMUR® necks to increase the potential range of motion.

23. In making the 2001 design change to the PROFEMUR® modular necks, Wright changed the geometry, weight, and mass of the PROFEMUR® modular necks.

24. More than 40,000 of the above-referenced modular necks "designed in 1985," and "successfully implanted in over 50,000 patients," and for which Wright

claimed, "none of the necks has experienced a clinical failure since their inception," were of the original design that existed prior to the 2001 design change.

25. In fact, prior to the year 2001, Wright had received notice of clinical failures in the form of fractures of modular necks that had been implanted in patients in Europe but continued to represent to surgeons that no failures had occurred clinically.

26. In its initial 510(k) Premarket Notification application to distribute its PROFEMUR® modular necks in the United States, Wright did not disclose to the FDA that it had notice of clinical failures in the form of modular neck fractures that had been implanted in patients in Europe.

27. Once Wright filed its 510(k) Premarket Notification application to distribute its PROFEMUR® modular necks in the United States, Wright had a duty to report to the FDA any instances it knew, or received notice of, a clinical failure in the form of a fracture of a modular neck that had been implanted in a patient.

28. Once Wright began distributing its PROFEMUR® modular necks in the United States, Wright had a duty to report to the FDA any instances it knew, or received notice of, a clinical failure in the form of a fracture of a modular neck that had been implanted in a patient.

29. Prior to April 19, 2005, Wright did not report to the FDA any of the instances it knew or received notice that a PROFEMUR® modular neck had

clinically failed by the modular neck having fractured in a patient in Europe.

30. On or about April 19, 2005, Wright first reported to the FDA a PROFEMUR® modular neck clinical failure where the modular neck implanted in a patient had fractured.

31. Wright received notice of additional modular neck clinical failures in the U.S. as a result of modular neck fractures.

32. The number of PROFEMUR® modular neck clinical failures in the form of modular neck fractures have continued to increase over time, and continues to increase to the present day, now numbering more than 800 such clinical failures.

33. Fractures have been reported for both the long and the short versions of the PROFEMUR® modular necks.

34. The fracture rate for PROFEMUR® long modular necks is approximately eight times the fracture rate of the PROFEMUR® short modular necks.

35. In Wright's Instructions for Use ("IFU") that accompanied the Device from their introduction into the United States, through 2008, if not later, Wright said that the Device was contraindicated for use in obese patients, "[W]here obesity is defined as three times normal body weight."

36. Prior to August 2010, Wright did not include a warning, precaution, or other advisory as to the use of any of its modular necks in people who weighed more

than a specifically stated weight in its IFUs distributed in the United States.

37. Prior to August 2010, Wright did not state that the use of any of its modular necks was contraindicated in heavyweight males in its IFUs distributed in the United States.

38. Prior to August 2010, Wright did not state that the use of any of its modular necks was contraindicated in patients who engaged in heavy lifting in its IFUs distributed in the United States.

39. Prior to August 2010, Wright did not state that the use of any of its modular necks was contraindicated in patients who engaged in impact sports in its IFUs distributed in the United States.

40. Even though some Wright IFUs for Devices in use prior to August 2010 contained a section titled, "Conditions presenting increased risk of failure include," that section of the IFU did not state that patients weighing more than a certain weight, engaging in a high level of physical activity, engaging in heavy lifting, or engaging in impact sports, would be at an increased risk of failure (fracture) of the modular neck.

41. Notwithstanding Defendant's knowledge, Defendant has never informed patients in the United States who received the PROFEMUR® modular necks, and have not yet experienced a modular neck fracture, that higher weight and/or higher levels of activity may place patients at an increased risk and rate of

failure due to fracture of the modular necks.

42. Notwithstanding Defendant's knowledge, Defendant has never directly asked its sales representatives/distributors or surgeons in the United States to directly inform any surgeons/patients who used/received these modular necks that patients of higher weight and/or higher levels of activity may be placed at an increased risk and rate of failure due to fracture of the modular necks.

43. Patient testimonials that have from time to time appeared on the Wright website and were available to Wright sales representatives/distributors, physicians, patients and the public from 2005 to the 2009, and/or that appeared in printed materials published by Wright from 2005 to the 2009, have represented that patients who received Wright artificial hips have already returned or are about to return to such activities as running, jogging, skydiving, snow skiing, water skiing, marathon running, tennis, racquetball, golf, horseback riding, work that involves lifting and moving of heavy objects, active military duty in Iraq, karate, competitive wrestling and competitive motocross racing, among other activities.

44. Patient testimonials that have from time to time appeared on the Wright website, and in printed materials published by Wright from 2005 to the 2009, have been from men who received the Devices and weighed in excess of 250 pounds.

45. In 2014, MicroPort Orthopedics, Inc. ("MicroPort") acquired Wright Medical's OrthoRecon Division, which was the hip division responsible for

designing and selling PROFEMUR® modular necks.

46. On August 11, 2015, MicroPort announced a voluntary recall of the Long 8° Varus Cobalt Chrome Modular Neck, model PHAC-1254, in the interest of "patient safety".

47. The August 11, 2015, notice issued by MicroPort Chairman, Dr. Zhaohua Chang, reported that "[a]s of the date of [the] announcement, MicroPort Orthopedics [had] received 28 reports of implant failures" related to the cobalt chrome neck.

48. On September 28, 2015, the FDA issued a Class 1 hip replacement recall of the PROFEMUR® Long Cobalt Chrome neck component, and advised patients to seek immediate medical treatment if they experience a sudden onset of severe pain in their post-operative hip.

PLAINTIFF CHRIS COLE'S PROFEMUR® DEVICE

49. Plaintiffs Chris Cole and Cristy Cole bring this product liability personal injury action as a recipient of a defective medical device, i.e., a modular prosthetic hip, designed, manufactured, and distributed by Defendant.

50. On or about April 4, 2007, Plaintiff Chris Cole had right total hip arthroplasty, at which time he had the Device properly implanted by Daniel Daluga, M.D., at Greater Lafayette Health Services Unity Surgical Center in Lafayette, Indiana. Specifically, Plaintiff received the PROFEMUR® 8 degree VAR/VAL

Long neck, model PHAO-1254, made from titanium alloy.

51. Based upon the patient population that Defendant intended its PROFEMUR® hip systems to be implanted in and at the time Plaintiff Chris Cole had the Device implanted, he was an appropriate patient to be implanted with this hip system.

52. Subsequent to the date of implant, Plaintiff Chris Cole used his Device in a normal and expected manner.

53. On or about February 12, 2019, the femoral neck of the Device suddenly and catastrophically failed, breaking into pieces.

54. At the time of this catastrophic failure, Plaintiff Chris Cole was performing a normal and expected activity of daily living.

55. On February 12, 2019, following the catastrophic failure of the device, Plaintiff Chris Cole was taken to the emergency department.

56. On February 13, 2019, Plaintiff Chris Cole's fractured Device was surgically removed by Dennis Blackburn, D.O., at Marian Regional Medical Center in Santa Maria, California, in a surgical procedure commonly called a "revision".

57. At the time the Device was implanted in Plaintiff Chris Cole, it was in the same condition in all relevant respects as when it left Wright's control.

58. The PROFEMUR® Total Hip System (and its components) implanted in Plaintiff Chris Cole was not merchantable and was unreasonably dangerous for

its intended and/or reasonably foreseeable uses in that:

A. It was and is unreasonably dangerous as a result of one or more of a combination of the following:

(1) the neck was designed in such a manner as to be subjected to excessive micromotion and fretting corrosion, thereby increasing the potential for failure;

(2) the surface of the section of the neck that was inserted into the femoral stem was designed in such a manner as to increase the potential for fretting and corrosion and failure;

(3) the portion of the neck that was inserted in the femoral stem was in a narrow, confined space, thereby increasing the potential for fretting, corrosion and failure;

(4) the components were designed in such a way as to make the modular neck component susceptible to fretting and corrosion, thereby increasing the potential for failure;

(5) the components were designed in such a way as to make the modular neck component susceptible to mechanically assisted crevice corrosion increasing the risk of fatigue fractures;

(6) the risk of neck fracture outweighed the utility of the Device;

(7) a reasonably prudent manufacturer or seller, given knowledge of

the Device's condition, would not have marketed or sold the Device; and

(8) there may be other conditions or defects yet to be determined.

B. The PROFEMUR® Total Hip Femoral System was dangerous to an extent beyond which would be contemplated by the ordinary consumer with the ordinary knowledge common to the community as to its characteristics in that:

(1) the ordinary consumer would not contemplate that the Device would catastrophically fail within less than eight years after implantation; and

(2) the ordinary consumer would not contemplate that the ordinary activities of daily living would result in the system catastrophically failing within less than eight years after implantation.

59. The Device is not designed to withstand the normal activities of daily living after implantation without premature failure from fractures.

60. The Device is not designed to withstand the normal activities of daily living after implantation in active or heavier weight patients without premature failure from fractures.

61. The Device was not tested in design and development at the level of forces that were known would be encountered in the normal activities of daily living.

62. The Device was not tested in design and development at the level of forces equal to the level of activities of patients that Wright promoted and marketed these devices to.

63. The Device was known by Defendant to be failing at higher than expected rates from fractures of the modular necks prior to the date of its implantation in Plaintiff Chris Cole.

64. Prior to the implant of the Device in Plaintiff Chris Cole, Wright did not warn patients, surgeons, customers, or its sales representatives/distributors that the Device was known to be failing from fractures at higher than expected rates.

65. Prior to the implant of the Device in Plaintiff Chris Cole, Wright did not warn patients, surgeons, customers, or its sales representatives/distributors that the Device was known to be failing from fractures in high activity or heavier weight patients at higher than expected rates.

66. Prior to the sudden catastrophic failure of Plaintiff Chris Cole's Device, Wright did not warn patients that the PROFEMUR® modular neck was known to be suddenly and catastrophically failing without warning from fractures during normal activities of daily living.

67. Prior to the sudden catastrophic failure of Plaintiff Chris Cole's Device, Wright did not warn patients that the PROFEMUR® modular neck was known to be suddenly and catastrophically failing without warning from fractures in high activity or heavier weight patients.

68. On or about February 12, 2016, the PROFEMUR® Total Hip Femoral System implanted in Plaintiff Chris Cole's right side catastrophically failed, i.e.,

fractured at the Neck, as a result of one or more of a combination of the foregoing unreasonably dangerous conditions.

69. As a direct and proximate result of the failure of the PROFEMUR® Total Hip System, Plaintiff Chris Cole has sustained injuries and damages including, but not limited to:

(a) undergoing surgery to remove and replace the failed prosthesis system;

(b) extended hospital stay including intensive care and inpatient rehabilitation;

(c) past and future pain and anguish, both in mind and in body;

(d) permanent physical disabilities;

(e) permanent diminishment of his ability to participate in and enjoy the affairs of life;

(f) medical bills associated with the replacement procedure and recovery therefrom;

(g) future medical expenses;

(h) loss of wages;

(i) loss of enjoyment of life;

(j) loss of past and future earnings and earning capacity;

(k) disfigurement; and

(l) physical impairment.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

70. Plaintiffs repeat, re-allege, and hereby incorporate by reference all of the allegations and statements contained in paragraphs 1-69 as though fully set forth herein.

71. At all times relevant hereto, Wright designed, manufactured, distributed, sold, marketed, and promoted the PROFEMUR® Total Hip Femoral System that was implanted in Plaintiff Chris Cole on or about April 4, 2007.

72. At all times relevant hereto, the PROFEMUR® Total Hip Femoral System was expected to, and did, reach prescribing physicians and consumers, including Plaintiff Chris Cole and Plaintiff's physician, without a substantial change in the condition in which it was sold.

73. At all times relevant hereto, Plaintiff Chris Cole and Plaintiff's healthcare providers used the PROFEMUR® Total Hip Femoral System for its intended or reasonably foreseeable purpose.

74. At all times relevant hereto, the PROFEMUR® Total Hip Femoral System was dangerous, unsafe, and defective in manufacture. Such defects included, but were not limited to, an unreasonably high propensity for corrosion, fretting, and fatigue under normal and expected use of the device, leading to fracture of the

modular neck and catastrophic failure of the device, requiring revision surgery.

75. Plaintiff Chris Cole is informed and believes, and thereupon alleges, that the PROFEMUR® Total Hip Femoral System implanted in Plaintiff was defectively manufactured because it differed from the manufacturer's design and specifications, or from typical units of the same product line.

76. As a direct, legal, proximate, and producing result of the defective manufacture of the PROFEMUR® Total Hip Femoral System implanted in Plaintiff Chris Cole, Plaintiff sustained injuries as set forth above.

77. The dangerous, unsafe, and defective manufacturing of the PROFEMUR® Total Hip Femoral System implanted in Plaintiff Chris Cole was a substantial factor in causing Plaintiff's injuries as set forth above.

SECOND CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

78. Plaintiffs repeat, re-allege, and hereby incorporate by reference all of the allegations and statements contained in paragraphs 1-69 as though fully set forth herein.

79. The PROFEMUR® Total Hip Femoral System was defective and unreasonably dangerous when it left the possession of Defendant in that it contained warnings insufficient to alert the medical community and patients, including Plaintiff Chris Cole and Plaintiff's healthcare providers, to the dangerous risks

associated with the PROFEMUR® Total Hip Femoral System when used for its intended and reasonably foreseeable purpose. The dangers and risks included, but were not limited to, an unreasonably high propensity for corrosion, fretting, cracking, and fatigue under normal and expected use of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

80. At all times relevant hereto, Plaintiff Chris Cole and Plaintiff's healthcare providers used the PROFEMUR® Total Hip Femoral System for its intended or reasonably foreseeable purpose.

81. Plaintiff Chris Cole and Plaintiff's healthcare providers could not have discovered any defect in the PROFEMUR® Total Hip Femoral System through the exercise of due care.

82. Defendant knew or should have known, by the use of scientific knowledge available before, at, and after the time of manufacture, distribution, and sale of the PROFEMUR® Total Hip Femoral System, of potential risks and side effects associated with the PROFEMUR® Total Hip Femoral System. Defendant knew or should have known of the defective condition, characteristics, and risks associated with said product, as previously set forth herein.

83. The warnings and instructions provided with the PROFEMUR® Total Hip Femoral System by Defendant did not adequately warn of the potential risks and

side effects of the PROFEMUR® Total Hip Femoral System, which risks were known or scientifically knowable to Defendant.

84. Defendant had a continuing duty to warn the medical community and public, including Plaintiff Chris Cole and Plaintiff's healthcare providers, of the potential risks and increased failure rate associated with the PROFEMUR® Total Hip System.

85. As a direct, legal, proximate, and producing result of Defendant's failure to warn, Plaintiff Chris Cole sustained injuries as set forth above.

86. Defendant's failure to adequately warn of the potential risks and side effects of the PROFEMUR® Total Hip Femoral System was a substantial factor in causing Plaintiff's injuries as set forth above.

THIRD CLAIM FOR RELIEF
NEGLIGENCE

87. Plaintiffs repeat, re-allege, and hereby incorporate by reference all of the allegations and statements contained in paragraphs 1-69 as though fully set forth herein.

88. At all times relevant hereto, Defendant designed, manufactured, distributed, sold, marketed, and promoted the PROFEMUR® Total Hip Femoral System for implantation into customers, such as Plaintiff Chris Cole, by physicians and surgeons in the United States.

89. At all times relevant hereto, Defendant knew or should have known that the novel design of the PROFEMUR® Total Hip Femoral System necessitated clinical trials and other pre-marketing evaluations of risks and efficacy. Such testing would have revealed the increased risks of failure and complications associated with the PROFEMUR® Total Hip Femoral System. A reasonable manufacturer under the same and similar circumstances would have conducted additional testing and evaluation of the PROFEMUR® Total Hip Femoral System's safety and performance prior to placing the PROFEMUR® Total Hip Femoral System into the stream of commerce.

90. At all times relevant hereto, Defendant knew or should have known of the serious complications and high failure rate associated with the PROFEMUR® Total Hip Femoral System. Despite receiving hundreds of reports of serious complications from healthcare providers, Defendant chose (1) not to perform any additional testing of the PROFEMUR® Total Hip Femoral System; (2) not to investigate other potential causes of the complications; (3) not to suspend sales or distribution; and (4) not to warn physicians and patients of the PROFEMUR® Total Hip Femoral System's unreasonably high propensity for corrosions, fretting, cracking, and fatigue under normal and expected used of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery and causing the damages stated herein.

91. As a direct, legal, proximate, and producing cause of Defendant's negligent design, testing, manufacturing, marketing, selling, and promoting the PROFEMUR® Total Hip Femoral System, Plaintiff suffered injuries as set forth above.

92. Defendant's negligent design, testing, manufacturing, selling, and promoting the PROFEMUR® Total Hip Femoral System, was a substantial factor in causing Plaintiff's injuries as set forth above.

FOURTH CLAIM FOR RELIEF
FRAUDULENT MISREPRESENTATION

93. Plaintiffs repeat, re-allege, and hereby incorporate by reference all of the allegations and statements contained in paragraphs 1-69 as though fully set forth herein.

94. The Defendant falsely and fraudulently represented to the medical and healthcare community, and to Plaintiff Chris Cole, Plaintiff's healthcare providers, and/or the FDA, that the PROFEMUR® Total Hip Femoral System had been properly tested and was safe and effective for its indicated use.

95. The representations made by Defendant to the medical and healthcare community and to Plaintiff Chris Cole, Plaintiff's healthcare providers, and/or the FDA, regarding the safety and performance of the PROFEMUR® Total Hip Femoral System were, in fact, false.

96. Defendant knew or should have known that the PROFEMUR® Total Hip Femoral System had not been sufficiently tested, was defectively designed, and lacked adequate warnings and instructions.

97. Defendant knew or should have known that the PROFEMUR® Total Hip Femoral System could and would cause severe and grievous injury to users of said product, and that the PROFEMUR® Total Hip Femoral System's inherent dangers exceeded any purported, inaccurate, and/or downplayed warnings.

98. When said representations were made by Defendant, Defendant knew those representations to be false and exhibited a willful, wanton, and reckless disregard for the truth of said representations.

99. Said representations were made by Defendant with the intent to defraud and deceive Plaintiff Chris Cole, Plaintiff's healthcare providers, the medical community, and the general public. Defendant intended said representations to induce Plaintiff, Plaintiff's healthcare providers, the medical community and the general public, to recommend, implant, and/or purchase the PROFEMUR® Total Hip Femoral System for use as part of total hip replacement surgery. Defendant's actions evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

100. At all relevant times, Plaintiff Chris Cole and Plaintiff's healthcare providers were unaware of the falsity of said representations and reasonably believed

them to be true.

101. In reliance upon Defendant's representations, Plaintiff Chris Cole was induced and did use the PROFEMUR® Total Hip Femoral System, thereby sustaining severe and permanent personal injuries, and is now at an increased risk of sustaining severe and permanent personal injuries in the future.

102. Defendant brought the PROFEMUR® Total Hip Femoral System to the market, and acted fraudulently, wantonly, and maliciously to the detriment of Plaintiff.

103. As a direct, legal, proximate, and producing result of Defendant's false representations, Plaintiff suffered the injuries set forth herein.

FIFTH CLAIM FOR RELIEF
FRAUDULENT CONCEALMENT

104. Plaintiffs repeat, re-allege, and hereby incorporate by reference all of the allegations and statements contained in paragraphs 1-69 as though fully set forth herein.

105. Defendant knew its representations were false or recklessly disregarded the truth of said representations.

106. In representations to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, Defendant omitted, concealed or suppressed material information regarding the safety and performance of the PROFEMUR® Total Hip Femoral

System, including, but not limited to:

(a) An unreasonably high propensity for corrosion, fretting and fatigue under normal and expected use for the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

(b) That the PROFEMUR® Total Hip Femoral System had an unacceptably high rate of failures requiring revision surgery;

(c) That the safety and performance of the PROFEMUR® Total Hip Femoral System was not adequately tested and/or known by Defendant;

(d) That patients implanted with the PROFEMUR® Total Hip Femoral System were at increased risk of experiencing painful and debilitating product failure and were more likely to undergo revision surgery than patients using other hip implant devices;

(e) The PROFEMUR® Total Hip Femoral System was designed, manufactured, marketed, promoted, distributed, and sold negligently, defectively, and/or improperly; and

(f) That safer alternatives were available.

107. Defendant purposefully downplayed and understated the serious nature of the risks associated with the use of the PROFEMUR® Total Hip Femoral System in order to increase and sustain sales.

108. Defendant had sole access to material facts regarding the safety and performance of the PROFEMUR® Total Hip Femoral System. Defendant knows Plaintiff and Plaintiff's healthcare providers and/or the FDA had no way to determine the truth behind Defendant's concealment, omission, and suppression of material facts as set forth herein.

109. Plaintiff and Plaintiff's healthcare providers relied on Defendant's incomplete and inaccurate representations as to the safety and performance of the PROFEMUR® Total Hip Femoral System when selecting, recommending, and implanting the PROFEMUR® Total Hip Femoral System.

110. As a direct, legal, proximate, and producing result of Defendant's concealment of material facts, Plaintiff has suffered injuries as set forth herein.

SIXTH CLAIM FOR RELIEF
NEGLIGENT MISREPRESENTATION

111. Plaintiffs repeat, re-allege, and hereby incorporate by reference all of the allegations and statements contained in paragraphs 1-96 as though fully set forth herein.

112. Defendant had a duty to truthfully represent to the medical community, and to Plaintiff, Plaintiff's healthcare providers, and the FDA, that the PROFEMUR® Total Hip Femoral System was not properly tested nor found to be safe and effective for its intended use.

113. Defendant knew or should have known that its representations regarding the safety and performance of the PROFEMUR® Total Hip Femoral System were, in fact, false.

114. Defendant failed to exercise ordinary care in determining the truth or falsity of its representations and by misrepresenting the safety and performance of the PROFEMUR® Total Hip Femoral System.

115. Defendant breached its duty to present truthful representations by knowingly, or by want of ordinary care, misrepresenting the safety and performance of the PROFEMUR® Total Hip Femoral System.

116. As a direct, legal, proximate, and producing result of Defendant's concealment of material facts, Plaintiffs have suffered injuries as set forth herein.

SEVENTH CLAIM FOR RELIEF
LOSS OF CONSORTIUM

117. Plaintiffs repeat, re-allege, and hereby incorporate by reference all of the allegations and statements contained in the preceding paragraphs as though fully set forth herein.

118. At all times herein mentioned, Plaintiffs Chris Cole and Cristy Cole were, and are, legally married as husband and wife.

119. As a direct and proximate result of Defendants' defective Profemur® Total Hip Femoral System and tortious conduct, and as a result of the injuries and

damages to Plaintiff Chris Cole arising therefrom, Plaintiff Cristy Cole has been deprived of the love, companionship, comfort, affection, society, solace or moral support, protection, loss of enjoyment of sexual relations, and loss of physical assistance in the operation and maintenance of the home, of her husband, Chris Cole, and has thereby sustained and will continue to sustain damages.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendant as follows:

1. For general damages for personal injuries to Plaintiff, according to proof;
2. For all past, current, and future medical and incidental expenses, according to proof;
3. For all past, current and future loss of wages, according to proof;
4. For punitive and/or exemplary damages in an amount sufficient to punish Defendant and deter similar conduct in the future, according to proof;
5. Loss of consortium;
6. For prejudgment interest, as provided by law;
7. For reasonable attorneys' fees;
8. For costs of litigation; and

9. For such other and further relief as this Court may deem just and proper.

Dated: 4/28, 2020

Respectfully submitted,

By: _____

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Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury to the full extent permitted by law.

Dated: 4/28, 2020

Respectfully submitted,

By: _____

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